REMARKS

Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 are pending in the present application. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description;
2. Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by WO 01/37654 (hereinafter, "the Tobias application"); and
3. Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by by WO 01/96584 (hereinafter, "the Mushegian application").

Applicant notes that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the amended or cancelled Claims (or similar Claims) in the future.

1. Rejection of Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 under 35 U.S.C. §112(1)

Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 are rejected under 35 U.S.C. §112(1) for failing to comply with the written description requirement. The Examiner has maintained the rejection and states that Applicants previous arguments were not persuasive because they were not commensurate with the scope of the claims. Office Action, p. 3.

As a threshold matter, the claims have been amended to specify that the dsRNA is orally active and targets for genetic inhibition a *Heterodera glycines* embryonic lethal phenotype gene. Applicants again note that this application provides many specific examples of *Heterodera glycines* that fall within the scope of the claims. The Examiner is referred to Table 1, pp. 35-37, which specifically lists suitable sequences corresponding to *Heterodera glycines* embryonic lethal phenotype genes and to Examples 1, 2, and 3, which describe the cloning of such genes

from *Heterodera glycines.* The structure (i.e., the sequence) and the function of these sequences is described. The sequences presented are representative of the genus. The Examiner cites the MPEP: "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. . . . 'One must define a compound by 'whatever characteristics sufficiently distinguish it'". By providing a number of specific *Heterodera glycines* sequences that fall within the scope of the claims, and by describing transgenic plants incorporating these sequences, the inventors established that they were in possession of the claimed invention. The embryonic lethal phenotype sequences have been defined by their nucleotide sequence and are representative of a genus of such sequences. Accordingly, this rejection should be withdrawn.

Applicants also respectfully submit that the Examiner has failed to address Applicants arguments regarding the applicability of *Eli Lilly* and the Federal Circuit's recent holding in *Falkner v. Inglis*, 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). In that case, the Federal Circuit specifically held that "*Eli Lilly* does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." Id. at 1367. The Federal Circuit specifically held that "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." Id. In the instant case, sequences within the claims were known in the art and reference sequences were described in the specification (see, e.g., Table 2 of the Specification, and the Specification at page 33, line 23 through page 34, line 13) and identified in the claims. That is all the written description that is needed.

As such, one of skill in the art would conclude that the Inventors were in possession of the necessary common attributes possessed by the members of the genus, and therefore the instant specification meets the written description requirement for these claims. The Applicants respectfully request these rejections be withdrawn.

2. Rejection of Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 under 35 U.S.C. §102(b)

Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by WO 01/37654 (hereinafter, "the Tobias application"). The Examiner found Applicant's previous arguments unpersuasive because "the dsRNA used by Tobias does effect nematode development and reproduction. Tobias et al. specifically teaches transgenic plants expressing a dsRNA for *M. incognita* unc-17 encoding vesicular acetylcholine transporter; if this gene is absent or mutated, proper development of the nematode is stopped." Office Action, pp. 4-5. The Examiner further finds that "on pages 8-9, [Tobias] states suitable nematode target genes include cell cycle genes and embryo lethal mutants (see paragraph bridging pages 8 and 9)."

The independent claims have been amended to specify that the claimed dsRNAs target *Heterodera glycines* embryonic lethal phenotype genes and that the dsRNAs are orally active. Tobias et al. does not provide a single sequence from *Heterodera glycines,* much less a sequence for an embryonic lethal phenotype gene from *Heterodera glycines,* or provide any data demonstrating that the prophetic M. incognita unc-17 sequences are orally active. Instead, the only working example provided by Tobias (Example 7, pp. 36-37) describes soaking *M. cognita* in a solution of the dsRNA. Accordingly, Tobias does not teach each element of the pending claims and the anticipation rejection is improper.

Applicants also respectfully submit that the Tobias is not enabled for the teachings suggested by the Examiner. The Examiner states that "On page 6, lines 29-32, Tobias teaches that the uptake of the dsRNA by the parasitic nematode induces silencing of the genes important for nematode growth, survival, or reproduction, thereby preventing nematode damage to the plant." Office Action, p. 5. The cited passages from Tobias do not demonstrate this – Tobias contains no data showing that nematode damage to a plant is inhibited.

Applicants further submit that Tobias is not enabled for teaching one of skill in the art how to make and use orally active dsRNA sequences that target *Heterodera glycines* embryonic lethal phenotype genes. No sequences for *Heterodera glycines* embryonic lethal phenotype genes are provided in the specification. Further, there is not example or data that shows the inhibition of nematodes feeding on soybeans. To be a valid anticipating reference, the prior art must be enabling. *Advanced Display Systems, Inc., v. Kent State University*, 54 USPQ2d 1673 (Fed. Cir. 2000). Accordingly, the anticipation rejection is improper and should be withdrawn.

3. Rejection of Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 under 35 U.S.C. §102(a)

Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 are rejected under 35 U.S.C. §102(a) as being anticipated by the Mushegian application. The Examiner states that: "On page 4, the last full paragraph, Mushegian et al. teach that the dsRNA molecules are for inhibiting genes useful for nematode growth, development, parasitism or reproduction (see also genes/proteins listed in Appendix I on pages 54 to 58). Since the claims do [not] recite distinguishing identifying characteristics for the dsRNA that targets embryonic lethal gene, Mushegian et al. anticipate the claimed invention."

The Applicants respectfully disagree. As noted above, the Applicants have amended the claims to specify that the claimed dsRNAs target *Heterodera glycines* embryonic lethal phenotype genes and that the dsRNAs are orally active. As was the case with Tobias, Mushegian et al. does not provide a single sequence from *Heterodera glycines,* much less a sequence for an embryonic lethal phenotype gene from *Heterodera glycines.*

Applicants further submit that Tobias is not enabled for teaching one of skill in the art how to make and use orally active dsRNA sequences that target *Heterodera glycines* embryonic lethal phenotype genes. No sequences for *Heterodera glycines* embryonic lethal phenotype genes are provided in the specification. Further, there is not example or data that shows the inhibition of nematodes feeding on soybeans. To be a valid anticipating reference, the prior art must be enabling. *Advanced Display Systems, Inc., v. Kent State University*, 54 USPQ2d 1673 (Fed. Cir. 2000). Accordingly, the anticipation rejection is improper and should be withdrawn.

CONCLUSION

Each rejection of the Office Action mailed April 6, 2007 has been addressed. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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